

REMARKS

Applicant respectfully requests reconsideration. Claims 14, 18, 19, and 25-28 were previously pending and are still pending in this application. No claims have been amended or added. No new matter has been added.

Summary of Interview with Examiner

Applicant thanks the Examiner for the courtesy extended to Applicant and representatives in the interview conducted on February 16, 2011. Applicant and representatives discussed with the Examiner the rejections and prior art of record, and evidence that supports withdrawal of the rejections. Applicant has prepared this amendment consistent with the discussion of the rejections and evidence with the Examiner. Applicant also brought to the attention of the Examiner the discrepancy regarding the finality of the Office Action between the Office Action Summary page and page 8 of the Office Action mailed September 1, 2010. The Examiner indicated that the Office Action mailed September 1, 2010 is a non-final Office Action.

Rejections Under 35 U.S.C. §103

Claims 14, 18-19, and 25-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Brooke et al. (US Patent 6,328,992) in view of Travis (US Patent 6,541,510) and Turner (J Clin Pharmacol 1981; 21: 283S-291S). Applicant respectfully traverses the rejection.

The cited prior art does not provide all of the elements of the claimed invention

The prior art cited by the Examiner lacks at least two elements recited in the instant claims as amended. First, as acknowledged by the Examiner on page 4 of the Office Action, Brooke et al. does not teach that cannabichromene (CBC) is present as more than 30% of the cannabinoids in the composition, as instantly claimed. Travis et al. discloses CBC containing compositions, but does not teach that CBC is present as more than 30% of the cannabinoids in the compositions. The Examiner asserts that it would have been obvious "that the CBC amount would be higher because of

the teachings of Turner that CBC is the major cannabinoid in freshly harvested drug-type cannabis material, which would make the amount of 30% obvious". Applicant respectfully disagrees and maintains that CBC is not abundant in most mature cannabis plants.

Most cannabis plants are bred specifically for high and predominant THC content, and as a result, the second most abundant cannabinoid in most mature cannabis plants may comprise less than 2% of the total cannabinoids. A sampling of the cannabinoid composition during the life cycle of several cannabis plants reveals that the proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant (see, e.g., Table 1 of Vogelmann et al., *J. Nat. Prod.*, 1988, 51 (6), pp 1075–1079, cited in the Information Disclosure Statement dated June 5, 2008; and pages 19-20 and Figures 3A-C of WO 2009/125198, cited in the Information Disclosure Statement dated April 7, 2010). Vogelmann et al. clearly disclose that, in the flowering plant, (the cannabinoids predominate in the flowering heads) CBC is found in relatively small amounts (127 µg CBC v. 3575 µg THC). Accordingly, the use of a plant extract comprising greater than or equal to 30% CBC for treating a mood disorder is not obvious.

Second, Brooke et al. does not teach that CBC is useful for treating mood disorders. Brooke et al. recites that “[s]everal medicinal uses have been found for the active ingredients of cannabis, including the ingredients tetrahydrocannabinol (THC), cannabinol (CBN), cannabidiol (CBD) and cannabichromene (CBC)” (col. 1, lines 23-26, emphasis added). Brooke et al. further discloses that the medicinal uses of cannabis include, among a list of ten applications, stress and depression. Brooke et al. also states that THC is the “primary active ingredient of cannabis” (col. 1, lines 42-44). Applicant respectfully asserts that Brooke et al. makes no comment on the activity of each of the specified ingredients of cannabis, and thus the person of ordinary skill in the art would not obtain any suggestion from Brooke to use CBC for treating any particular disorder, let alone for treating the specific disorder recited in the instant claims. In particular, Brooke et al. does not teach that CBC is useful for treating mood disorders. Merely because cannabis is taught to have a number of medicinal uses, and CBC is listed as one of the active ingredients (though not the “primary”

active ingredient), it does not follow that CBC is useful for treating all indications mentioned in Brooke.

Established case law states that “[A] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art”. KSR Int'l v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). “The fact that a claimed product is within the broad field of the prior art and one might arrive at it by selecting specific items and conditions does not render the product obvious in the absence of some directions or reasons for making such selection.” Ex parte Kuhn, 132 USPQ2d 1958 (Bd App 1961). Furthermore, the Examiner is not entitled to use the claim as a “frame” and to employ “individual, naked parts of separate prior art references...as a mosaic to recreate a facsimile of the claimed invention.” W. L. Gore & Assoc., Inc, v. Garlock, Inc., 721 F.2d 1540, 1552 (Fed. Cir., 1984). The combination of Brooke et al. and Turner does not provide any reason or direction to the skilled person to select both CBC and mood disorders with the expectation that CBC would be effective in treating such disorders. Further, there is no reason that a skilled person could take from this combination of references to use CBC that is substantially pure or is an extract from a cannabis plant that contains greater than or equal to 30% CBC of the total cannabinoid content. Moreover, since Travis teaches that CBC containing compositions can be used as anti-virals, Travis does not provide one of skill in the art with any reason or direction to use CBC for treating other disorders, let alone for treating mood disorders as recited in the instant claims.

There are dozens of cannabinoids known in cannabis (see, e.g., Wikipedia entry at [<http://en.wikipedia.org/wiki/Cannabinoid>]; copy submitted to the Office on September 11, 2009). In particular, this document shows the existence of 67 cannabinoids (see “Table of natural cannabinoids” at pages 7-10) and reports on page 2 that “At least 66 cannabinoids have been isolated from the cannabis plant (see page 2, citing to reference 4, Burns and Ineck, *Annals Pharmacother.*, 40:251-260, 2006). Absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one or more cannabinoids would be useful in treating mood disorders, and would not have had a reasonable expectation of success in randomly selecting

cannabinoids to try. Brooke et al. teaches that “cannabis” (and not CBC) can be used for potentially treating a number of medical indications. Similarly, neither Travis nor Turner et al. teach or suggest using CBC for treatment of a mood disorder.

Motivation to combine the cited references and a reasonable expectation of success are absent

In addition, the skilled person would not have been motivated to make the claimed invention due to the link between cannabis and depression in the art as was stated in the previously-filed Whittle Declaration (see paragraphs 5-6, and 11c). At the time the instant invention was filed, there was evidence in the art which suggested that cannabis was responsible for mental health problems. According to Professor Henry, a consultant in toxicology from St Mary's Hospital in London, there was a fourfold increase in major depression in regular cannabis smokers (see BBC news article at [<http://news.bbc.co.uk/2/hi/health/2923647.stm>], cited in the Information Disclosure statement filed herewith). Consumption of cannabis was found to be associated with an increase in anxiety, depression and suicide attempts (see e.g., Rey et al. Br J Psychiatry. 2002 Mar;180:216-21, cited in the Information Disclosure statement filed herewith). Accordingly, the skilled person would not have had a reasonable expectation of success in using CBC to treat mood disorders. In fact, it is more likely given the link between cannabis and mental illness that the skilled artisan would have been prejudiced against selecting any cannabinoid, including CBC, to use as a medicine to treat mood disorders.

Thus, the combination of cited art does not provide the elements of the claimed invention, does not provide the requisite motivation to combine the cited references, does not provide the skilled person with a reason to use CBC in the claimed methods, and does not provide a reasonable expectation of success in doing so. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 14, 18-19, and 25-28 are rejected under 35 U.S.C. §103(a) as being unpatentable over Whittle et al. (US Pg/Pub 2005/0042172) in view of Turner et al. (J Clin Pharmacol 1981; 21: 283S-291S).

The cited prior art does not provide all of the elements of the claimed invention

The prior art cited by the Examiner lacks at least two elements recited in the instant claims as amended. First, as acknowledged by the Examiner on page 6 of the Office Action, Whittle et al. does not teach that cannabichromene (CBC) is present as more than 30% of the cannabinoids in the composition, as instantly claimed. The Examiner asserts that “Turner teaches that CBC is one of the most abundant naturally occurring cannabinoids; therefore, it would be obvious that the content of CBC would be higher to treat a mood disorder.” Applicant respectfully disagrees and maintains that the level of CBC is very low in mature plants and certainly lower than the claimed amount.

As discussed above, the use of a plant extract comprising greater than or equal to 30% CBC for treating a mood disorder is not obvious. CBC is not abundant in most mature cannabis plants and a sampling of the cannabinoid composition during the life cycle of several cannabis plants reveals that the proportion of CBC in the total cannabinoid fraction decreases with ageing of the plant (see, e.g., Table 1 of Vogelmann et al., J. Nat. Prod., 1988, 51 (6), pp 1075–1079, cited in the Information Disclosure Statement dated June 5, 2008; and pages 19-20 and Figures 3A-C of WO 2009/125198, cited in the Information Disclosure Statement dated April 7, 2010). Vogelmann et al. clearly disclose that, in the flowering plant, (the cannabinoids predominate in the flowering heads) CBS is found in relatively small amounts (127 µg CBS v. 3575 µg THC). Most cannabis plants are bred specifically for high and predominant THC content, and as a result, the second most abundant cannabinoid in most mature cannabis plants may comprise less than 2% of the total cannabinoids. Thus, the combined teachings of Whittle et al., and Turner et al. do not contain each element of treating a mood disorder in a human patient with CBC that is substantially pure or is an extract from a cannabis plant containing greater than or equal to 30% CBC of the total cannabinoid content.

Second, Whittle et al. does not link any specific cannabinoid to treatment of depression, and more importantly, does not link the use of CBC to treatment of depression. Paragraph [0056] in Whittle et al. is the only passage that mentions depression at all, and it states that compositions comprising cannabis extract, natural or synthetic cannabinoids or mixtures thereof can be administered for the treatment of “pain unresponsive to opioid analgesics, pain arising from

neuropathic and neurogenic conditions, dysmenorrhoea, inflammatory pain, particularly that associated with rheumatoid arthritis, depression, migraine, asthma, epilepsy, post-operative pain, glaucoma, chemotherapy-induced nausea and vomiting, relief of pain and muscle spasm in multiple sclerosis, and loss of appetite and anorexia, particularly in AIDS patients.” Merely because compositions comprising cannabis extracts are taught to have a number of medicinal uses, it does not follow that CBC is useful for treating all disclosed indications let alone for treating a mood disorder, which is not specifically described in Whittle et al.

Indeed, as indicated above, at least 66 different cannabinoids have been isolated from the cannabis plant, and there is no expectation that each of these cannabinoids can treat all disclosed indications. Absent some teaching pointing to specific cannabinoids, the skilled person would not have known which one or more cannabinoids would be useful in treating mood disorders.

Moreover, as discussed above, established case law states that “[A] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art”. KSR Int'l v. Teleflex Inc., 82 USPQ2d 1385, 1396 (2007). “The fact that a claimed product is within the broad field of the prior art and one might arrive at it by selecting specific items and conditions does not render the product obvious in the absence of some directions or reasons for making such selection.” Ex parte Kuhn, 132 USPQ2d 1958 (Bd App 1961). Furthermore, the Examiner is not entitled to use the claim as a “frame” and to employ “individual, naked parts of separate prior art references...as a mosaic to recreate a facsimile of the claimed invention.” W. L. Gore & Assoc., Inc, v. Garlock, Inc., 721 F.2d 1540, 1552 (Fed. Cir., 1984). The combination of Whittle et al. and Turner does not provide any reason or direction to the skilled person to select both CBC and mood disorders with the expectation that CBC would be effective in treating such disorders. Further, there is no reason that a skilled person could take from this combination of references to use CBC that is substantially pure or is an extract from a cannabis plant that contains greater than or equal to 30% CBC of the total cannabinoid content.

Motivation to combine the cited references and a reasonable expectation of success are absent

In addition, the Examiner has failed to establish that one of ordinary skill in the art would have been motivated to make the claimed invention and would have recognized that the results of the combination were predictable. The link between cannabis and depression in the art, as was stated in the previously-filed Whittle Declaration (see paragraphs 5-6, and 11c), would have prejudiced the skilled artisan against selecting CBC to use as a medicine to treat mood disorders. At the time the instant invention was filed, there was some evidence in the art which suggested that cannabis was responsible for mental health problems. According to Professor Henry, a consultant in toxicology from St Mary's Hospital in London, there was a fourfold increase in major depression in regular cannabis smokers (see BBC new article at [<http://news.bbc.co.uk/2/hi/health/2923647.stm>], cited in the Information Disclosure statement filed herewith). Consumption of cannabis was found to be associated with an increase in anxiety, depression and suicide attempts (see e.g., Rey et al. Br J Psychiatry. 2002 Mar;180:216-21, cited in the Information Disclosure statement filed herewith). Accordingly, the skilled person would not have had a reasonable expectation of success in using CBC to treat mood disorders.

Thus, the combination of cited prior art does not provide the elements of the claimed invention, does not provide the requisite motivation to combine the cited references, does not provide the skilled person with a reason to use CBC in the claimed methods, and does not provide a reasonable expectation of success in doing so. Accordingly, withdrawal of this rejection is respectfully requested.

Double Patenting Rejection

Claims 14, 18-19, and 25-28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 12, and 14 of copending Application No. 11/760,364.

The claims in US 11/760,364 recite administration of an entirely different cannabinoid, cannabigerol (CBG), which is structurally different than the compound recited in the claims as

amended of the instant application (see e.g., Table showing main classes of natural cannabinoids of Wikipedia entry at [<http://en.wikipedia.org/wiki/Cannabinoid>]; copy submitted to the Office on September 11, 2009). Applicant maintains that the use of CBC for treating mood disorders is not obvious in view of the use of CBG in US 11/760,364.

MPEP § 2144.09 states that “[a]n obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.’ In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). See In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)”. However, where the compounds are dissimilar in structure, such as in the case of CBC and CBG, there is no expectation that the compounds will have similar properties. Thus, the use of CBC for treating mood disorders is not obvious in view of the use of CBG in US 11/760,364.

Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. H0664.70032US00.

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